Frequently Asked Questions about Smallpox

What should I know about Smallpox?

Vaccination is not recommended, and the vaccine is not available to health providers or the public. In the absence of a confirmed case of smallpox anywhere in the world, there is no need to be vaccinated against smallpox. There also can be severe side effects to the smallpox vaccine, which is another reason we do not recommend vaccination. In the event of an outbreak, the CDC has clear guidelines to swiftly provide vaccine to people exposed to this disease. The vaccine is securely stored for use in the case of an outbreak. In addition, Secretary of Health and Human Services Tommy Thompson recently announced plans to accelerate production of a new smallpox vaccine.

Are we expecting a smallpox attack?

We are not expecting a smallpox attack, but the recent events that include the use of biological agents as weapons have heightened our awareness of the possibility of such an attack.

Is there an immediate smallpox threat?

At this time we have no information that suggests an imminent smallpox threat.

If I am concerned about a smallpox attack, can I go to my doctor and request the smallpox vaccine?

The last naturally acquired case of smallpox occurred in 1977. The last cases of smallpox, from laboratory exposure, occurred in 1978. In the United States, routine vaccination against smallpox ended in 1972. Since the vaccine is no longer recommended, the vaccine is not available. The CDC maintains an emergency supply of vaccine that can be released if necessary, since post-exposure vaccination is effective.

Are there plans to manufacture more vaccine in case of a bioterrorism attack using smallpox?

Yes. In 2000, CDC awarded a contract to a vaccine manufacturer to produce additional doses of smallpox vaccine.

If someone comes in contact with smallpox, how long does it take to show symptoms?

The incubation period is about 12 days (range: 7 to 17 days) following exposure. Initial symptoms include high fever, fatigue, and head and back aches. A characteristic rash, most prominent on the face, arms, and legs, follows in 2-3 days. The rash starts with flat red lesions that evolve at the same rate. Lesions become pus-filled after a few days and then begin to crust early in the second week. Scabs develop and then separate and fall off after about 3-4 weeks.

Is smallpox fatal?

The majority of patients with smallpox recover, but death may occur in up to 30% of cases.

How is smallpox spread?

In the majority of cases, smallpox is spread from one person to another by infected saliva droplets that expose a susceptible person having face-to-face contact with the ill person. People with smallpox are most infectious during the first week of illness, because that is when the largest amount of virus is present in saliva. However, some risk of transmission lasts until all scabs have fallen off.

Contaminated clothing or bed linen could also spread the virus. Special precautions need to be taken to ensure that all bedding and clothing of patients are cleaned appropriately with bleach and hot water. Disinfectants such as bleach and quaternary ammonia can be used for cleaning contaminated surfaces.

If someone is exposed to smallpox, is it too late to get a vaccination?

If the vaccine is given within 4 days after exposure to smallpox, it can lessen the severity of illness or even prevent it.

If people got the vaccination in the past when it was used routinely, will they be immune?

Not necessarily. Routine vaccination against smallpox ended in 1972. The level of immunity, if any, among persons who were vaccinated before 1972 is uncertain; therefore, these persons are assumed to be susceptible. For those who were vaccinated, it is not known how long immunity lasts. Most estimates suggest immunity from the vaccination lasts 3 to 5 years. This means that nearly the entire U.S. population has partial immunity at best. Immunity can be boosted effectively with a single revaccination. Prior infection with the disease grants lifelong immunity.

How many people have not had the vaccination?

Approximately half of the U.S. population has never been vaccinated.

Is it possible for people to get smallpox from the vaccination?

No, smallpox vaccine does not contain smallpox virus but another live virus called Vaccinia virus. Since this virus is related to smallpox virus, vaccination with vaccine provides immunity against infection from smallpox virus.

How safe is the smallpox vaccine?

Smallpox vaccine is considered very safe. However, some people with pre-existing conditions such as eczema or immune system disorders have a higher risk for having complications from the vaccine. Adverse reactions have been known to occur that range from mild rashes to rare fatal encephalitis and disseminated Vaccinia. Smallpox vaccine should not be administered to persons with a history or presence of eczema or other skin conditions, pregnant women, or persons with immunodeficiency diseases and among those with suppressed immune systems as occurs with leukemia, lymphoma, generalized malignancy, or solid organ transplantation.

Is there any treatment for smallpox?

There is no proven treatment for smallpox, but research to evaluate new antiviral agents is ongoing. Patients with smallpox can benefit from supportive therapy (e.g., intravenous fluids, medicine to control fever or pain) and antibiotics for any secondary bacterial infections that may occur.

Is there a test to indicate if smallpox is in the environment like there is for anthrax?

Various agencies are currently validating tests designed to test for the smallpox virus in the environment.

If smallpox is discovered or released in a building, or if a person develops symptoms in a building, how can that area be decontaminated?

The smallpox virus is fragile and in the event of an aerosol release of smallpox, all viruses will be inactivated or dissipated within 1-2 days. Buildings exposed to the initial aerosol release of the virus do not need to be decontaminated. By the time the first cases are identified, typically 2 weeks after the release, the virus in the building will be gone. Infected patients, however, will be capable of spreading the virus and possibly contaminating surfaces while they are sick. Therefore, standard hospital grade disinfectants such as quaternary ammonias are effective in killing the virus on surfaces should be used for disinfecting hospitalized patients' rooms or other contaminated surfaces. Although less desirable because it can damage equipment and furniture, hypochlorite (bleach) is an acceptable alternative. In the hospital setting, patients' linens should be autoclaved or washed in hot water with bleach added. Infectious waste should be placed in biohazard bags and autoclaved before incineration.

What should people do if they suspect a patient has smallpox or suspect that smallpox has been released in their area?

Report suspected cases of smallpox or suspected intentional release of smallpox to your local health department. The local health department is responsible for notifying the state health department, the FBI, and local law enforcement. The state health department will notify the CDC.

How can we stop the spread of smallpox after someone comes down with it?

Symptomatic patients with suspected or confirmed smallpox are capable of spreading the virus. Patients should be placed in medical isolation so that they will not continue to spread the virus. In addition, people who have come into close contact with smallpox patients should be vaccinated immediately and closely watched for symptoms of smallpox. Vaccine and isolation are the strategies for stopping the spread of smallpox.

What is the smallpox vaccine, and is it still required?

The vaccine against smallpox is made with a virus related to smallpox virus called *Vaccinia* virus. It is not made with smallpox virus called *Variola*. The vaccine is a highly effective immunizing agent against smallpox infection. It was successfully used to eradicate smallpox from the human population.

Should I get vaccinated against smallpox?

Vaccination is not recommended at this time, and the vaccine is not available to healthcare providers or to the public. In the absence of a confirmed case of smallpox anywhere in the world, there is no need to be vaccinated against smallpox. CDC has clear guidelines for providing vaccine to people exposed to smallpox if a case did occur. Healthcare workers and close contacts of the person or persons with confirmed smallpox disease would receive the vaccine. Through CDC, healthcare workers would have access to the vaccine if it were needed to prevent the disease.

Many vaccinations are required, why don't people get the smallpox vaccine?

The last known naturally occurring case of smallpox occurred in Somalia in 1977. In May 1980, the World Health Assembly certified that the world was free of naturally occurring smallpox. By the 1960s, because of vaccination programs and quarantine regulations, the risk for importation of smallpox into the United States had been reduced. As a result, recommendations for routine smallpox vaccination were rescinded in 1971. In 1976, the recommendation for routine smallpox vaccination of health-care workers was also discontinued. In 1982, the only active licensed producer of *Vaccinia* vaccine in the United States discontinued production for general use, and in 1983, distribution to the civilian population was discontinued. All military personnel continued to be vaccinated, but that practice ceased in 1990. Since January 1982, smallpox vaccination has not been required for international travelers, and International Certificates of Vaccination forms no longer include a space to record smallpox vaccination.

Is the smallpox virus, Variola, that causes smallpox still around?

Although smallpox disease has been eradicated, two countries still keep smallpox virus *(Variola)* stocks. Two laboratories hold stocks of smallpox virus *(Variola)*. These are the WHO Collaborating Centers in Atlanta, USA and Koltsovo, Russian Federation.

Are some people still receiving the smallpox vaccination today?

Yes. *Vaccinia* vaccine is recommended for laboratory workers who directly handle cultures, animals contaminated or infected with, nonhighly attenuated Vaccinia virus, recombinant *Vaccinia* viruses derived from nonhighly attenuated Vaccinia strains, or other orthopoxviruses that infect humans. These would include monkeypox, cowpox, *Vaccinia*, and *Variola*. Other health-care workers, such as physicians and nurses whose contact with nonhighly attenuated *Vaccinia* viruses is limited to contaminated materials such as medical dressings but who adhere to appropriate infection control measures, are at lower risk for accidental infection than laboratory workers. However, because a theoretical risk for infection exists, vaccination can be offered to this group. Vaccination is not recommended for people who do not directly handle nonhighly attenuated virus cultures or materials or who do not work with animals contaminated or infected with these viruses.

What are the risks of the smallpox vaccines? Are there side effects?

Side effects from successful vaccination, particularly in those receiving their first dose of vaccine, include tenderness, redness, swelling, and a lesion at the vaccination site. In addition, the vaccination may cause fever for a few days and the lymph nodes in the vaccinated arm may become enlarged and tender. These symptoms are more common in those receiving their first dose of vaccine (15%–20% of those vaccinated) than in those being re-vaccinated (5%–10% of those vaccinated). The overall risks of serious complications of smallpox vaccination are low, and occur more frequently in those receiving their first dose of vaccine, and among young children. The most frequent serious complications are encephalitis (brain inflammation), progressive destruction of skin and other tissues at the vaccination site, and severe and destructive infection of skin affected already by eczema or other chronic skin disorder. The complication of encephalitis occurs in about one in 300,000 doses in children and one in 200,000 doses in adults. The vaccine is not recommended for those who have abnormalities of their immune system because the complication of progressive destruction of skin and other tissues at the vaccination site has occurred only among recipients in this group. The vaccine is also not recommended for recipients who have eczema or other chronic skin disorders because the complication of severe and destructive infection of skin has occurred only among recipients in this group.

Do other countries have smallpox vaccine stores?

In addition to the stock of smallpox vaccine in the US, an additional 50–100 million doses are estimated to exist worldwide. Many countries still hold smallpox vaccine *(Vaccinia)* stocks. WHO recommends that countries that still have stocks of smallpox vaccine *(Vaccinia)* maintain these stocks. This recommendation has been made for two reasons. Firstly, small amounts of vaccine are still needed to vaccinate laboratory personnel handling *Vaccinia* virus and other members of this virus family. Some of these viruses are found in nature and cause illness among animals, and some are used in research to make new, safer vaccines against a variety of infectious diseases. Secondly, smallpox vaccine, *Vaccinia*, will also be needed in case of a deliberate or accidental release of smallpox virus, *Variola*.

What are the symptoms of smallpox?

Variola virus causes smallpox. The incubation period is about 12 days with a range of 7 to 17 days following exposure. Initial symptoms include high fever, fatigue, and head and back aches. A characteristic rash, most prominent on the face, arms, and legs, follows in 2–3 days. The rash starts with flat red lesions that evolve at the same rate. Lesions become pus-filled and begin to crust early in the second week. Scabs develop and then separate and fall off after about 3–4 weeks. Most patients with smallpox recover, but death occurs in up to 30% of cases.

What is the HHS/CDC smallpox plan? When will it be released? Does the plan address mass vaccination?

CDC has been preparing for some time for the remote possibility of an outbreak of smallpox as an act of terror. That process has intensified since September 11, 2001. Although we are planning for this possibility to protect public health, we have no indication that there is an imminent threat. As part of the ongoing effort to increase awareness, CDC has distributed a draft of a smallpox preparedness plan to reviewers for comment. It will then be reviewed by state health departments, which will participate in its implementation. However, if needed, it could be put in operation immediately.

Does the death rate differ for those who have been vaccinated from those who have not?

For people exposed to smallpox, the vaccine can lessen the severity or even prevent illness if it is given within 4 days after exposure. Vaccine administered after exposure has been shown to provide significant protection against death from smallpox.

Should you get the smallpox vaccine if you're immuno-compromised?

No, not unless there is a smallpox outbreak. Vaccinations could cause deaths in people with weakened immune systems: those undergoing chemotherapy, organ transplant patients, and those with AIDS. There is no need to take that risk until there is evidence of an outbreak. But the U.S. should have the vaccine ready if needed as an "insurance policy."

How long does a smallpox vaccination last?

It is not known exactly how long the immunity from the smallpox vaccination will last. Most estimates suggest that immunity lasts from three to five years.

Is every American going to be vaccinated for smallpox?

If there is an outbreak of smallpox, vaccinations of people may only be needed in the area around the cases of smallpox to contain the spread. If health officials are not able to contain the outbreak, vaccination of a wider group of people may be required. U.S. health officials are increasing the stock of smallpox vaccine to be ready to vaccinate as needed.

How many people would have to get smallpox before it is considered an outbreak?

One suspected case of smallpox is considered a public health emergency. Smallpox surveillance in the United States includes detecting a suspected case or cases, making a definitive diagnosis with rapid laboratory confirmation at CDC, and preventing further smallpox transmission. A suspected smallpox case should be reported immediately by telephone to state or local health officials. They should immediately obtain advice regarding isolation of the patient or patients, and on laboratory specimen collection. State or local health officials should notify CDC **immediately** at (404) 639-2184 or (404) 639-0385 if a suspected case of smallpox is reported.

What should be done if there is a smallpox outbreak?

If an outbreak occurs, the first step would be to properly isolate those with the disease. Health officials should be diligent regarding use of adequate isolation facilities and precautions. If they are at all uncertain about correct procedures for isolating patients, they should contact the state or local health department or CDC. All the contacts of the patients should be vaccinated as soon as possible. In the event that there are many cases in a city vaccinations may be given to the entire population of that city.

What should be done to isolate someone with smallpox?

Isolation of confirmed or suspected smallpox patients will be necessary to limit the potential exposure of nonvaccinated and, therefore, nonimmune persons.

Airborne precautions using correct ventilation including negative air-pressure rooms with high-efficiency particulate air filtration should be initiated for hospitalized confirmed or suspected smallpox patients, unless the entire facility has been restricted to smallpox patients and recently vaccinated persons.

Although personnel who have been vaccinated recently and who have a demonstrated immune response should be fully protected against infection with smallpox virus, they should continue to observe standard contact precautions including using protective clothing and shoe covers when in contact with smallpox patients or contaminated materials to prevent inadvertent spread of Variola virus to susceptible persons and potential self-contact with other infectious agents.

Personnel should remove and correctly dispose of all protective clothing before contact with nonvaccinated people.

Reusable bedding and clothing can be autoclaved or laundered in hot water with bleach to inactivate the virus.

Laundry handlers should be vaccinated before handling contaminated materials.

Nonhospital isolation of confirmed or suspected smallpox patients should be of a sufficient degree to prevent the spread of disease to nonimmune persons during the time the patient is considered potentially infectious, which includes from the onset of symptoms until all scabs have separated.

Private residences or other nonhospital facilities that are used to isolate confirmed or suspected smallpox patients should have nonshared ventilation, heating, and air-conditioning systems. Access to those facilities should be limited to recently vaccinated persons with a demonstrated immune response. If suspected smallpox patients are placed in the same isolation facility, they should be vaccinated to guard against accidental exposure caused by misclassification as someone with smallpox.

In addition to isolation of infectious smallpox patients, careful surveillance of contacts during their potential incubation period is required.

Transmission of smallpox virus rarely occurs before the appearance of the rash that develops 2–4 days after the initial fever.

If a vaccinated or unvaccinated contact experiences a fever >101° F (38° C) during the 17-day period after his or her last exposure to a smallpox patient, the contact should be isolated immediately to prevent contact with nonvaccinated or nonimmune persons until smallpox can be ruled out by clinical or laboratory examination.

Will ciprofloxacin protect me against smallpox?

No. Because smallpox is a virus, antibiotics such as ciprofloxacin will not fight the smallpox infection. The only cure is to get the vaccine within a few days of exposure to the virus.

If the decision is made that everyone needs to be vaccinated, how will this occur and who will pay for it?

There will be a systematic administration of the vaccine that will be paid for by the United States government.

Is there a test to indicate whether smallpox is in the environment like there is for anthrax?

Scientists believe that if smallpox virus is released as an aerosol and not exposed to UV light, it may persist for as long as 24 hours or somewhat longer under favorable conditions. However, by the time patients become ill, which takes about 10 days to 12 days after infection with the virus, and it has been determined that an aerosol release of smallpox virus had occurred, there would be no viable smallpox virus left in the environment to detect. Trying to detect the virus everywhere at all times without any indications of any illness in people would not be feasible.

The occurrence of smallpox infection among people who handled laundry from infected patients is well documented, and it is believed that virus in such material remains viable for extended periods. In this situation, the virus could be detected in the environment, but investigators would already know it was there because of the presence of the associated illness.

In studies conducted during the smallpox eradication program and by surveillance for cases in newly smallpox-free areas it was reasoned that if the virus were able to persist in nature and infect humans, there would be cases occurring for which no source could be identified. Cases of this type were not observed. When cases were found, there were human cases in people who had direct contact with another infected person.

When will additional smallpox vaccine be ready?

President Bush's recent budget request (October 17, 2001) proposed spending $509 million to speed the development and acquisition of smallpox vaccine in order to reach any American potentially exposed to the virus in a potential bioterrorist attack. Currently, more than 15 million doses of smallpox are available. The additional funds will allow the department to stockpile as much vaccine as needed to protect the nation in the event of an outbreak of smallpox.

Is there a test to determine whether or not you have any protection from smallpox from vaccinations received years ago?

No. Routine vaccination against smallpox ended in 1972. The level of immunity, if any among persons who were vaccinated before 1972 is uncertain; therefore, these persons are assumed to be susceptible. For those were vaccinated, it is not known how long immunity lasts. Most estimates suggest that vaccination protection lasts from 3 to 5 years. Immunity can be boosted effectively with a single revaccination. Prior infection with the disease grants lifelong immunity.

Is smallpox contagious before the smallpox symptoms show?

Smallpox patients are most infectious during the first week of the rash. At this time, patients have sores in their mouths. These sores release smallpox virus into the patient's saliva. The virus may spread through the air when the infected person breathes, talks, laughs, or coughs. A patient is no longer infectious after all scabs have fallen off, usually about 3 or 4 weeks after the start of the rash.

Symptoms of smallpox begin 12-14 days (range 7-17 days) after exposure. The disease starts with 2-3 days of high fever and extreme tiredness with severe headache and backache. The rash usually begins about 2-4 days after the fever and, at first, is a few red spots on the face and forearms and in the mouth. It then spreads to the trunk and legs. Sores might form on the palms and soles as well. By the fourth day of rash, the spots have turned to blisters (vesicles), and by the seventh day the blisters turn to pustules (blisters filled with pus). Smallpox skin sores are deeply embedded in the skin (dermis) and feel like firm round objects in the skin. The pustules form scabs by the fourteenth day. As the sores heal, the scabs separate and pitted scarring gradually develops.

What is the difference between a "live vaccine" and a "killed vaccine"?

There are two basic types of vaccines: live (live-attenuated) and killed (inactivated).

Live vaccines are made from viruses or bacteria, sometimes called "wild," that cause disease. These wild viruses or bacteria are weakened in a laboratory.

Live vaccine works when the virus replicates in the body of a vaccinated person. This turns on the immune system and prepares the body to fight the disease when exposed to it. The immune response to a live vaccine is almost the same as from natural infection. Sometimes a person getting a live vaccine has mild symptoms of the disease.

Live vaccines rarely may cause severe or fatal reactions as a result of uncontrolled replication (growth) of the vaccine virus. This may occur in persons with weak immune systems, including persons with leukemia or human immunodeficiency virus (HIV) infection or persons undergoing treatment with certain drugs. This is why it is so important to know a person's health status before giving a live vaccine.

Currently available live vaccines include measles, mumps, polio, rubella, Vaccinia (smallpox), varicella (chickenpox), and yellow fever. All of these are made from viruses. There are two live bacterial vaccines: 1) Bacillus of Calmette and Guérin (BCG) vaccine for tuberculosis and 2) oral typhoid.

Killed vaccines are made by growing bacteria or virus and then treating it with heat and/or chemicals (usually formalin). These vaccines cannot cause disease from infection, even in someone with a weakened immune system.

Killed vaccines always require multiple doses. The first dose does not produce protective immunity. It "primes" the immune system, getting it ready to react. A protective immune response develops after the second or third dose.

Available killed vaccines include acellular pertussis, anthrax, botulism, cholera, diptheria, hepatitis A, hepatitis B, *Haemophilus influenzae* type b (Hib), influenza, Lyme disease, meningococcus, pertussis, plague, pneumococcus, polio, rabies, tetanus, typhoid, and typhoid VI.

If people got the vaccination when it was available in the past, will they be immune?

Not necessarily. It is not clear how long protection from smallpox vaccine lasts. Most experts believe that protection from vaccination lasts 3 to 5 years. Persons who were vaccinated before 1972 may have some protection against smallpox, but it is uncertain. This means that the U.S. population has partial immunity at best. Immunity can be boosted with a single revaccination. Routine vaccination against smallpox ended in 1972.

If someone had smallpox once, are they immune? Would they need the vaccine?

Most people who have had smallpox disease are protected from the disease for life and do not need to be vaccinated. However, few people living in the United States have had smallpox.

Is it possible for someone to receive the smallpox vaccine and have it not "take," i.e., work? How does someone who has been vaccinated for smallpox know that he or she is immune or that the vaccine has "taken"?

Evaluating a person's immunity against smallpox is difficult. In the past, a process called "re-challenging" was the only way to know for sure that a person was still protected. Smallpox vaccination causes a small blister or vesicle to form at the site of the vaccination. When a vaccinated person was "challenged" with a second dose of vaccine in another location and did not develop the telltale scar, then that person was thought to be immune to the virus. The formation of a second blister or vesicle indicated the first vaccination did not take and resulted in a lack of immunity.

Today, it is possible to gauge immunity induced by the smallpox vaccine by measuring levels of antibodies to the virus. However, the absence of antibodies to smallpox on a blood test does not mean that there is not some lingering immunity to the virus, since a person could still have a type of immunity called cellular immunity. Even in the absence of antibodies, the body’s cells may be sensitized to smallpox and capable of triggering a protective reaction when exposed to the virus.

Are diluted doses of smallpox vaccine as effective?

It is possible that diluted (i.e., watered-down) smallpox vaccine may also be effective in providing immunity. Studies are currently under way to determine the effectiveness of diluted vaccine.

Would a more diluted smallpox vaccine be an effective booster shot?

It is possible that diluted (i.e., watered-down) smallpox vaccine may also be effective as a booster shot. Results from the dilution studies will help make this determination.

How soon will results be available for dilution studies on the smallpox vaccine?

Results from these studies are expected by early 2002.

What is the smallpox vaccine made of?

Dryvax is the name of the smallpox vaccine that is currently licensed for use in the United States. It is a live-virus preparation of infectious Vaccinia virus made by Wyeth Laboratories, Inc., Marietta, Pennsylvania. Vaccinia vaccine does not contain smallpox (Variola) virus and cannot cause smallpox.

Is there a risk of accidental exposure to persons involved in the production of smallpox vaccine?

Persons involved in the production of smallpox vaccine will not contract smallpox because the vaccine does not contain smallpox virus. The vaccine contains another live virus called Vaccinia virus. Because Vaccinia is closely related to smallpox, vaccination with that virus provides immunity against infection from smallpox virus.

However, as with all live-virus vaccines, the Vaccinia vaccine does carry some risks. To minimize any risk of infection, the limited number of facilities involved in the production of smallpox vaccine should always observe appropriate biosafety guidelines and adhere to published infection-control procedures and recommendations for working with the vaccine virus strain.

Why are health responders being vaccinated against smallpox, but the general public is not?

A small group of CDC workers has recently received the smallpox vaccine so that they will be prepared to respond in the event of a bioterrorist attack involving smallpox. Smallpox vaccine is not available to health care providers or the public. In the absence of a confirmed case of smallpox anywhere in the world, there is no need to be vaccinated against smallpox. CDC maintains an emergency supply of vaccine that can be released if necessary. For smallpox, post-exposure vaccination is effective. In the event of an outbreak, CDC has clear guidelines to swiftly provide vaccine to people exposed to this disease. In addition, Tommy Thompson, U.S. Secretary of Health and Human Services, recently announced plans to accelerate production of a new smallpox vaccine.

Who is asking for volunteers to receive the smallpox vaccine? Who should people call if interested in volunteering?

The National Institutes of Health, together with the University of Maryland, the St. Louis University School of Medicine, the University of Rochester School of Medicine, and the Baylor College of Medicine, have recruited volunteers to participate in studies examining the effectiveness of diluted preparations of smallpox vaccine. The vaccine for the study will be provided by CDC.